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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
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09/728,553

12/02/2000

Peter M. Bonutti

BON-4363

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05/14/2004

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EXAMINER

LEWIS, AARON J

ART UNIT

PAPER NUMBER

3743

DATE MAILED: 05/14/2004

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Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/728,553

Applicant(s)

BONUTTI, PETER M.

Examiner

AARON J. LEWIS

Art Unit

3743

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 02/24/2004 (AMENDMENT).
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 100-106, 169-175, 177-194, 199-217 and 223-242 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☒ Claim(s) 171-175; 177; 179-194; 200; 201; 205; 209; 210; 213-217; 223-242 is/are allowed.
- 6) ☒ Claim(s) 100-106; 169, 170, 178, 199, 202-204; 206; 208, 211 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

1. Applicant's election with traverse of claims 100-106, 169-194, 223-242 in Paper No. 05 is acknowledged. The traversal is on the ground(s) that a search and examination of the entire application can be made without serious burden. This is not found persuasive because there are at least four distinct inventions defined by all of the claims in the instant application and each with a separate utility and separate classification; accordingly, restriction for examination purposes is deemed to be proper.

The requirement is still deemed proper and is therefore made FINAL.

Claim Rejections - 35 USC § 102

2. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

3. Claims 100-106 are rejected under 35 U.S.C. 102(b) as being anticipated by Anderson ('362).

As to claim 100, Anderson discloses a method of treating a patient, said method comprising moving a leading end portion (27) of a member (23) disposed in a patient's body (fig.5) relative to body tissue, said step of moving a leading end portion of a member relative to body tissue includes attracting the leading end portion of the member with a magnetic field (41) emanating from a location outside of the patient's body (fig.5).

As to claim 101, Anderson discloses the step of attracting a leading end portion (27) of the member (23) includes inducing the leading end portion of the member to move from a position offset to one side of an opening into the opening (col.6, lines 27-40).

As to claims 102 and 103, Anderson as discussed above with respect to claim 101, also discloses the further step of applying force against a trailing end portion of the member (23) to move the member relative to body tissue, and steering (by deflecting the leading end portion as illustrated in fig.5) the leading end portion of the member relative to the body tissue under the influence of the magnetic field emanating from a location outside of the patient's body as the member moves relative to the body tissue under the influence of the force applied against the trailing end portion of the member. The steps of sliding and inserting member (23) as expressly disclosed in Anderson (col.6, lines 27-40) inherently include manual manipulation of member (23) at a portion thereof which is readable upon a trailing end portion in an effort to slide and/or insert member (23) further into a patient's trachea.

As to claim 104, while Anderson does not expressly disclose a step of moving the magnetic field relative to a patient's body, it is submitted that a step of moving the field (41) is inherent in the method of intubation in Anderson because as the leading end portion (27,37) is inserted further into a patient's throat, the external magnetic field must also be moved downwards in order to maintain control over the leading end portion during guiding of the leading end portion through a patient's larynx and into a patient's trachea.

As to claim 105, Anderson as discussed above with respect to claims 102-103 also discloses the step of applying force against a first portion (i.e. inherently include manual manipulation of member (23) at a portion thereof outside a patient's mouth which is readable upon a first portion in an effort to slide and/or insert member (23) further into a patient's trachea), and changing a path of movement of the member relative to the body tissue (fig.5) while continuing to move the member relative to the body tissue under the influence of force applied (i.e. manual manipulation) to the first portion of the member, said step of changing the path of movement of the member relative to the body tissue includes attracting a second portion (#39,37 of fig.5) of the member with a magnetic field (41) having a source disposed outside of the patient's body.

As to claim 106, while Anderson does not expressly disclose a step of moving the magnetic field relative to a patient's body, it is submitted that a step of moving the field (41) is inherent in the method of intubation in Anderson because as the leading end portion (27,37) is inserted further into a patient's throat, the external magnetic field must also be moved downwards in order to maintain control over the leading end portion during guiding of the leading end portion through a patient's larynx and into a patient's trachea.

4. Claims 169,170,178,202-204 are rejected under 35 U.S.C. 102(b) as being anticipated by White ('636).

As to claim 169, White discloses a method of tracheal intubation, said method comprising the steps of positioning a plurality of detectors (col.9, lines 17-21) in an array adjacent to an outer surface of a patient's neck, moving a tracheal tube (18) relative to

Art Unit: 3743

the patient's respiratory system along an insertion path which extends from the patient's pharynx, through the patient's larynx and into the patient's trachea, emitting (32) an output at a leading end position (figs. 1, 11, 18) of the tracheal tube as the tracheal tube moves along the insertion path, detecting (figs. 15, 17) the output emitted at a leading end portion of the tracheal tube with detectors of a plurality of detectors (col. 9, lines 17-21), and determining the position of the leading end portion of the tracheal tube along the insertion path as a function of the relationship of the emitted output detected by one detector of the plurality of detectors to the emitted output detected by another detector of the plurality of detectors.

As to claim 170, White discloses the step of emitting an output at a leading end portion of the tracheal tube (18) includes emitting a magnetic field from a magnet (20) connected with the leading end portion of the tracheal tube.

As to claim 178, White discloses the step of positioning a plurality of detectors in an array adjacent to an outer surface of the patient's neck (col. 9, lines 17-21). This array is disclosed as being arranged over the thyroid cartilage of the patient; accordingly, (inasmuch as the thyroid cartilage is consistent with the Adam's apple) this array of detectors inherently extends at least part way around the patient's Adam's apple.

As to claim 202, White discloses an apparatus for use in tracheal intubation of a patient, said apparatus comprising a tracheal tube which is moveable along an insertion path into a patient's trachea, an emitter (20) which provides an output, and a detector (22) which responds to the output from said emitter, a first one of said emitter (20) and said detector being connected with said tracheal tube (#18 of fig. 7) for movement

Art Unit: 3743

therewith along the inserting path, a second one of said emitter and said detector (22) being disposed adjacent to an outer surface of the patient's neck (figs.11,14-18) during movement of said tracheal tube along the insertion path.

As to claim 203, White discloses the emitter (20) includes a magnet that emits a magnetic field and said detector (22) includes a device that responds to a magnetic field.

As to claim 204, White discloses the emitter to be connected with a leading end portion of said tracheal tube (18) for movement along the insertion path.

5. Claim 199 is rejected under 35 U.S.C. 102(b) as being anticipated by Berci ('153).

As to claim 199, Berci discloses an apparatus for use in tracheal intubation, said apparatus comprising a tracheal tube (figs.3,4), sensor means (22) connected with said tracheal tube for determining the position of the leading end portion of said tracheal tube during movement of said tracheal tube along an insertion path which extends from a patient's pharynx, through the patient's larynx and into the patient's trachea (fig.4), and steering means (54) connected with a leading end portion of said tracheal tube for applying force against the leading end portion (col.6, lines 7-16) of said tracheal tube (fig.3) during movement of said tracheal tube along the insertion path.

Claim Rejections - 35 USC § 103

6. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the

Art Unit: 3743

invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

7. Claim 206 is rejected under 35 U.S.C. 103(a) as being unpatentable over White ('636).

As to claim 206, while White does not expressly disclose sensor (22) to be a Hall effect device for measuring magnetic field generated by magnet (20), it is submitted that the detector circuit illustrated in fig.6 is exemplary of a circuit which is typically employed to demonstrate the Hall effect and is therefore, readable upon a Hall effect device. That is, the magnetic field of magnet (20) would be imposed onto the current within the circuit of fig.6 in an effort to demonstrate whether the current within the circuit of fig.6 is due to electrons or holes.

8. Claims 208,211 are rejected under 35 U.S.C. 103(a) as being unpatentable over White ('636) in view of Acker ('938).

As to claim 208, White discloses an apparatus for use in tracheal intubation of a patient, said apparatus comprising a tracheal tube (18) which is movable along an insertion path into a patient's trachea, an emitter (20) connected with a leading end portion of said tracheal tube, said emitter being effective to provide an output during movement of said tracheal tube along the insertion path, and a plurality of detectors in an array adjacent to the patient's Adam's apple (col.9, lines 17-21), each detector of said plurality of detectors being responsive to the output from said emitter and means connected with said plurality of detectors for determining the position of the leading end portion of said tracheal tube along the insertion path as a function of outputs from said

plurality of detectors during movement of said tracheal tube along the insertion path (figs.11,14-18).

The difference between White and claim 208 is a micro-processing unit connected with said plurality of detectors.

Acker (col.10, lines 28-31) teaches a micro-processing unit (44) connected to a plurality of detectors for determining the position of a probe within a patient's respiratory system. The micro-processing unit transforms the location of the distal end of the probe into the frame of reference of the image [of the surrounding portions of the patient's respiratory system] and prepares a composite display including at least a portion of the image and representation of the probe superposed on the image.

It would have been obvious to modify the detectors of White to connect a micro-processing unit thereto because it would have provided a means for transforming the location of the distal end of the probe into the frame of reference of the image of the surrounding portions of the patient's respiratory system and preparing a composite display including at least a portion of the image and representation of the probe superposed on the image as taught by Acker.

As to claim 211, White discloses the emitter to include a magnet (20) which emits a magnetic field, each of said detectors (22) of said plurality of detectors being responsive to the magnetic field emitted by said magnet.

Allowable Subject Matter

9. Claims 171-175; 177; 179-180; 181-188; 189-191; 192-194; 200; 201; 205; 209; 210; 213-217; 223-224; 225-230,233-241; 231; 232; 242 are allowed.

Response to Arguments

10. Applicant's arguments filed 02/24/2004 have been fully considered but they are not persuasive. Applicant's assertion that Anderson lacks a step of controlling the magnetic field strength is disagreed with because one of ordinary skill having the disclosure of Anderson would have realized that a step of controlling the magnetic field strength is inherent in the mere movement of the magnet along a the outer surface of a patient's neck in an effort to cause the distal end of the stylet to move into the entrance to the trachea inasmuch as one of ordinary skill would have to move the outer magnet (41) until its field becomes effective enough (i.e. strong enough through a patient's neck tissues as "seen" by the distal end of the stylet) to actually cause movement of the distal end of the stylet into the tracheal entrance. That is, that act of manually manipulating the external magnet (41) to cause movement of the distal end of the stylet requires one of ordinary skill to move the external magnet around the external surface of a patient's neck over areas of varying thickness of neck tissue which together inherently includes the controlling of the magnetic field.

Applicant's arguments with respect to claim 169 are disagreed with because White (col.6, lines 1-15 and col.9, lines 17-21) discloses providing a display (22,32) illustrating a position of a leading end portion (20) of the tracheal tube relative to the patient's trachea during at least a portion of said step of moving the tracheal tube relative to the patient's respiratory system.

Applicant's assertion that White lacks a magnetic flux detector on the stylet and means for producing magnetic flux external to the patient, i.e. on the supresternal notch

Art Unit: 3743

of the patient may be accurate; however, this assertion is not commensurate with the language of the claim inasmuch as no such limitations are present. The language of the claim recites a first one of an emitter and detector being connected with the tracheal tube and a second one of an emitter and detector being disposed adjacent to an outer surface of the patient's neck. This language is being read (interpreted) as disposing a first one of an emitter OR a detector being connected with the tracheal tube and a second one of an emitter OR detector being disposed adjacent to an outer surface of the patient's neck. A review of the instant specification finds support for such an interpretation but does not provide support for the combination of emitter and detector on the tracheal tube AND the combination of emitter and detector being disposed adjacent to an outer surface of a patient's neck. Finally, the claim language does not recite a patient's suprasternal notch.

Applicant's arguments regarding claim 199 are disagreed with because the sensor means (22) of Berci is readable upon the claimed sensor means inasmuch as it is "connected" with a tracheal tube as illustrated in figs.3 and 4 of Berci.

11. Applicant's arguments with respect to claims 208,211 have been considered but are moot in view of the new ground(s) of rejection.

Conclusion

12. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

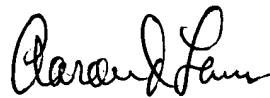
A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within

TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to AARON J. LEWIS whose telephone number is (703) 308-0716. The examiner can normally be reached on 9:30AM-6:00PM M-F.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, HENRY A. BENNETT can be reached on (703) 308-0101. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).


AARON J. LEWIS
Primary Examiner
Art Unit 3743

Application/Control Number: 09/728,553

Art Unit: 3743

Page 12

Aaron J. Lewis

May 11, 2004